UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff,

v. Case No. 10-CR-253

CONRAD E. LEBEAU,

Defendant.

DECISION AFFIRMING JUDGMENT

Conrad LeBeau pled guilty to one misdemeanor count of introducing into interstate commerce a new drug that had not been approved by the Food and Drug Administration (FDA). *See* 21 U.S.C. §§ 331(d), 333(a)(1), 355(a). LeBeau's conviction relates to his distribution of "Perfect Colon Formula #1," which he promoted as reducing food allergies. (*See* Information at 5.) LeBeau's plea, before U.S. Magistrate Judge William E. Callahan, was conditioned on being allowed to appeal various matters he had raised in motions before the magistrate judge. Following entry of judgment, LeBeau appealed, and the case was assigned to this court. LeBeau represents himself on appeal.

APPELLATE PROCEDURAL BACKGROUND

A person convicted before a U.S. magistrate judge has an appeal as of right to the district court. 18 U.S.C. §§ 3402, 3742(h). In reviewing such an appeal, the district court shall apply the Federal Rules of Appellate Procedure. Fed. R. Crim. P. 58(a), (g)(2)(D); *see* § 3742(h); *United States v. Shelton*, No. 05-mc-00310, 2007 WL 328812, *4 (N.D. Ill. Jan. 31, 2007). Rule 58 provides that the defendant is not entitled to a trial de novo by the

district judge. Instead, the scope of the appeal is the same as in an appeal to the court of appeals. Fed. R. Crim. P. 58(g)(2)(D).

Upon receipt of the case, this court determined that LeBeau's appeal should be treated like an appeal to the U.S. Court of Appeals for the Seventh Circuit. This court directed the parties to designate the record and to brief the appeal as they would an appeal to the Seventh Circuit. The order referenced Fed. R. App. P. 28 and 32 and Circuit Rules 28(c) and 32 (7th Cir.) and included copies of the rules for LeBeau's benefit. (Doc. 91.)

This court intended the parties to frame and discuss the issues on appeal rather than incorporate by reference all or any of the documents in the record. Magistrate Judge William Callahan had issued three separate decisions regarding several motions, and one of the briefs before Judge Callahan contained over seventy pages and several others contained over twenty-five pages. This court wanted the parties to narrow the issues on appeal and to succinctly present their arguments.

Neither party complied with their directions, LeBeau filed a brief that was difficult to understand. He spent pages discussing the legislative history and text of the Pure Food Act of 1906, even adding language to and rewording the text of the 1906 Act "to clarify and limit the breadth of the definition to the intended labeling targets of the law." (Doc. 98 at 10-11.) Yet he did not sufficiently discuss the text of the statutes under which he was convicted. LeBeau discussed the pharmaceutical industry's influence on Congress and the Center for Drug Evaluation and Research (Doc. 98 at 2-3), allegedly untruthful answers by the FDA to FOIA requests (*id.* at 5), and the contents of fourteen articles found at the National Library of Medicine (*id.* at 7-9). He conflated several constitutional issues. (*See id.* at 6 ("This practice pre-empts the First Amendment and the ultimate effect is 'restraint

of trade' that is not a power granted to Congress under Article I, Sec 8 of the U.S. Constitution. Restraint of trade by abridging freedom of the press violates not only the first amendment rights of the defendant, but also 'freedom of choice in medicine' reserved by the defendant under the 9th amendment. It further violates rights reserved to the states under the 10th.").) And LeBeau confusingly questioned and argued whether the label on his Perfect Colon Formula changed the product's material composition and whether a flyer he wrote about Perfect Colon Formula actually was a drug. (*Id.* at 17-20.[1]) Instead of focusing on the issues he preserved in his plea agreement, narrowing the issues for this court on appeal, and arguing legal errors he believed Magistrate Judge Callahan made, LeBeau expanded the issues on appeal. Moreover, in his conclusion, LeBeau asked this court to allow him to withdraw his guilty plea. (Doc. 98 at 30.)

The United States filed a six-page brief stating its position that except for one issue, its prior briefs in the case had sufficiently addressed all issues, that those prior briefs (Docs. 37, 45, 68, and 76) were incorporated by reference, and that this court should "summarily adopt the reasoning set forth in Magistrate Judge Callahan's decisions of September 21, 2011, December 7, 2011, and May 29, 2012." (Doc. 99 at 2.) According to the government, "LeBeau's arguments have been fully-litigated and Magistrate Judge Callahan's reasoning is both compelling and comprehensive. There is no good reason to

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[1]LeBeau wrote:

> Since the facts clearly indicate that the composition of Perfect Colon Formula is not a drug, it is the label that has to be the drug. . . .
>
> There is one small problem here – the label is not intended for ingestion. There are no instructions to throw away what is inside the bottle and eat the label to "reduce food allergies." Therefore, there is nothing about Perfect Colon Formula that is a drug. Its composition is not a drug and the label that has words on it that violate the law as it is currently applied is not intended to be ingested, therefore the label is not a drug either. . . . So what is the drug?

(Doc. 98 at 20.)

spill more ink before this case reaches the court of appeals." (*Id.*) However, the government did address a case referenced by LeBeau that was decided after Magistrate Judge Callahan ruled. (*Id.* at 3-5.)

As a result, this court found it difficult to discern the issues LeBeau is appealing, what his arguments were, and what the government's position was. To focus the arguments, the court conducted a hearing at which LeBeau said he wished to pursue three matters on appeal: (1) the "doctrine of overbreadth," (2) the "doctrine of legal impossibility," and (3) restraint of trade and "constitutional violation." The court then directed LeBeau to file a new brief refining his arguments on appeal and the government to respond in detail to those arguments.

The case has now been rebriefed. Although LeBeau still seeks to incorporate prior filings in the case (*see*, *e.g.*, Doc. 113 at 3-4 (stating his issues on appeal and that they were discussed in documents 28, 43, 58, 75, and 98), 4 (directing the court to a certain discussion in document 28), 14 ("For my arguments on the Doctrine of Overbreadth, see Doc 28 and 43 for the applicable sections. For a comparison of the Caronia case to mine, see Doc 98[,] pages 22 to 30.")),[2] this court can now better grasp his arguments.

The following discussion is based primarily on the revised briefs, although the original appellate briefs (but not necessarily the documents incorporated by reference) have received some consideration. Also, the court reviewed several of the briefs before Magistrate Judge Callahan. To the extent that the court has missed some variation of

[2]The government also refers this court to prior briefing for "more extensive briefing" of the First Amendment issue and "a more complete explanation of why a patent is not required." (Doc. 114 at 10 n.5, 11 n.6.) However, the argument in the government's final brief to this court had already adequately set forth the government's position and authority on the First Amendment issue.

either party's argument not mentioned in the briefs before this court but buried in the briefs before Magistrate Judge Callahan, such argument is deemed waived. At the in-court hearing on appeal, the parties were directed to set forth all of their arguments in the briefs to this court and notified that they would not receive broad review of prior documents. Just as the court is not required to scour the record for evidence creating a question of fact, *Hunt-Golliday v. Metro. Water Reclamation Dist.*, 104 F.3d 1004, 1010 n.2 (7th Cir. 1997), it should not be required to scour the record to find the parties' arguments.

In his revised brief (Doc. 113), LeBeau lists five issues for appeal: (1) the doctrine of impossibility (both factual and legal); (2) the doctrine of overbreadth; (3) violations of his First Amendment right to free speech and Fifth Amendment right to due process (and "other issues"); (4) *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980); and (5) *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012). (Doc. 113 at 3-4.) However, numbers (4) and (5) above are better considered as legal support for issue (3) rather than separate issues.

The court is limiting LeBeau to these issues. While LeBeau's revised brief on appeal invites this court to review and comment on "[t]he balance of all the other legal argument reserved in Doc 58 and in Docs 28 and 43" (Doc. 113 at 14), this court declines his invitation regarding any matter not addressed in this decision. To the extent LeBeau briefly references additional issues in his revised reply brief ("freedom of choice in medicine under the 9th amendment" and restraint of trade (Doc. 116 at 14, 18)) but did not list them in his revised initial brief (Doc. 113) or properly develop them even if mentioned, this court will not address them. When it ordered re-briefing, this court told LeBeau that he would be limited to what he raised in his revised brief, and that the government should respond.

New arguments in reply are not permitted. *United States v. Cruse*, 805 F.3d 795, 818 n.7 (7th Cir. 2015);

In this instance, this court is functioning as an appellate court and will review legal issues de novo and factual determinations with deference to the magistrate judge. *United States v. Snow*, 656 F.3d 498, 500 (7th Cir. 2011); *see United States v. Gochis*, 256 F.3d 739, 742 (7th Cir. 2001).

DISCUSSION

The Federal Food, Drug, and Cosmetic Act (FDCA) establishes a system of premarketing clearance for drugs. Certain drugs, designated as "new drugs," cannot be sold in interstate commerce unless a new-drug application is approved by the FDA. *United States v. Marcen Labs., Inc.*, 416 F. Supp. 453, 455 (S.D.N.Y.), *aff'd*, 556 F.2d 562 (2d Cir. 1976) (table).

The criminal information in this case charged LeBeau with introducing new drugs into interstate commerce in violation of the FDCA. LeBeau was convicted under 21 U.S.C. § 355(a), which states that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug." *See also* 21 U.S.C. § 331(d) (prohibiting the introduction of an unapproved new drug through interstate commerce). New drug applications are to be filed with the Secretary of Health and Human Services. 21 U.S.C. §§ 321(d), 355(b), (j). Any person may file an application. § 355(b).

As pertinent here, the term "drug" means an "article[] intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. § 321(g)(1)(B). "New drug" means any drug "the composition of which is such

that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." § 321(p)(1). Thus, the manufacturer or distributor of a product meant to diagnose, cure, mitigate, treat or prevent disease has two choices before distributing that product: show that the product is generally recognized among experts as safe and effective for that use or obtain approval from the Secretary. *See United States v. LeBeau*, 786 F. Supp. 761, 767 (E.D. Wis. 1992), *aff'd*, 985 F.2d 563, 1993 WL 21970 (7th Cir. 1993) (table).

Although the FDCA does not define what constitutes general recognition of safety and effectiveness, the Supreme Court has interpreted the new-drug definition to require expert consensus founded upon "substantial evidence," which in turn means adequate and well-controlled investigations by experts and responsible expert opinions. *United States v. Rutherford*, 442 U.S. 544, 546-47, n.1, 549 n.7 (1979); *LeBeau*, 786 F. Supp. at 772-73.

A new-drug application must include certain information regarding the drug. Further, "[t]he applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted." § 355(b). The applicant "shall amend the application" to include the patent number and expiration date if a patent claiming the drug or method of using the drug issues while a new-drug application is pending. *Id.*

Although in his most recent briefs LeBeau questions whether the phrase "'reduces food allergies' was really a disease claim" and says "a disease claim for Perfect Colon

Formula was never intended" (Doc. 113 at 5; *see also id.* at 6[3]), he pled guilty to the count and was not allowed to withdraw it. LeBeau's present suggestions that he did not intend the product to treat a disease and that a food allergy is not a disease condition are contradicted by the factual basis set forth in his plea agreement and during his plea hearing. He admitted in his plea agreement that he made a disease claim for Perfect Colon Formula, which evidenced his intended use for the product. (Doc. 58 at 2, 5.[4]) During LeBeau's plea hearing, he acknowledged that a claim of reducing food allergies is a disease claim. (Doc. 96 at 20-21.) LeBeau recognized in his plea agreement that the government could have demonstrated at trial beyond a reasonable doubt that Perfect Colon Formula qualified as a drug. (Doc. 58 at 2-6.)

A. Impossibility

On appeal, LeBeau contends that conviction under § 355(a) is factually and legally impossible. Regarding factual impossibility, LeBeau maintains that the tests and trials he would need for approval by the FDA are too costly for him (or anyone like him) to fund. As for legal impossibility, LeBeau asserts that a new-drug application requires a patent but that food products are not patentable, meaning that no food product can ever be approved as a new drug.

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[3]LeBeau says he never believed he was guilty of any wrongdoing and did not perceive "reduces food allergies" to be a disease claim when he used it because it was a truthful statement based on scientific research. (Doc. 113 at 6.)

[4]LeBeau admitted in the plea agreement that FDA investigators reviewed LeBeau's products on LeBeau's website and purchased a number of products for interstate shipment and that "[s]elected for purchase were products for which the defendants made 'disease claims' in violation of the FDCA. In particular, and as it relates to count three of the Information, the defendants claimed on their website that use of the product, Perfect Colon Formula #1, 'reduces food allergies.'" (Doc. 58 at 5.)

If factual impossibility is a defense, *see United States v. Tykarsky*, 446 F.3d 458, 465 (3d Cir. 2006) (stating that factual impossibility is not a defense, though in a different context), LeBeau has pointed the court to no evidence in the record supporting the defense. He says that he cannot afford the required tests and trials, but fails to point this court to evidence showing failed attempts to secure investors to fund testing. Instead, he raises questions as follows:

> Is it practical for the government to expect a defendant who could not afford to hire his own attorney in a criminal case to conjure up millions of dollars and file an NDA [new drug application] as well as pay for subsequent controlled studies to obtain FDA approval? Where would the defendant obtain the millions of dollars to comply with this demand under the law? Is not a demand that would impose an unrealistic and extreme economic burden on the defendant to comply with the law beyond the realm of what is possible?

(Doc. 113 at 7.) But compliance with the law *is possible*, even if LeBeau thinks it improbable. LeBeau *could* raise money or find an investor for necessary studies and trials. He just believes that excusing compliance would be preferable for his financial circumstances.

In any event, that tests and trials may cost a substantial amount of money is not a basis for ignoring the approval process. The FDCA is a consumer-protection statute. *See United States v. Gen'l Nutrition, Inc.*, 638 F. Supp. 556, 561 (W.D.N.Y. 1986); *United States v. 3 Cartons, More or Less, No. 26 Formula GM*, 132 F. Supp. 569, 574 (S.D. Cal. 1952). It should be liberally interpreted to effectuate its "high purpose" of protecting unwary consumers in vital matters of health. *United States v. Hohensee*, 243 F.2d 367, 370 (3d Cir. 1957); *see United States v. Dotterweich*, 320 U.S. 277, 280 (1943) (stating that the purposes of the FDCA "touch phases of the lives and health of people which, in the

circumstances of modern industrialism, are largely beyond self-protection."). Provisions establishing procedures for new drugs entering the marketplace "must be construed broadly to meet the Congressional purpose to keep inadequately tested medical and related products which might cause widespread danger to human life out of interstate commerce." *Gen'l Nutrition*, 638 F. Supp. at 561 (internal quotation marks omitted). LeBeau's personal or corporate financial interests do not overcome the government's interest in protecting the public from harmful products or unfounded claims of use.

As part of his factual impossibility argument, LeBeau contends that the FDA has never approved any unpatented drugs as new drugs, citing a Freedom of Information Act (FOIA) request made in 2011 and the response he received. LeBeau asked for a copy of a "document or file" that contained the names of all approved unpatented drugs or "the names of all ingestible items and foods of plant or animal origin from land or sea" approved as new drugs by the FDA between 1906 and 2010 for the prevention or treatment of disease. (Doc. 113 at 9.) The FDA's response indicated that its records began in 1938 and that a check of records of the Center for Drug Evaluation and Research "did not locate any files which contained non-patented drugs or ingestible items and foods of plant of (or) animal origin from land or sea." (Doc. 113 at 10.) LeBeau contends that this FOIA response shows that obtaining FDA approval for a food as a new drug must be impossible to obtain. (*See id.*)

Having apparently never applied for new-drug approval, LeBeau may lack standing to make this challenge. And further information regarding the records search conducted by the FDA is not in the record in this case. But, in any event, the FOIA request and response do not prove what LeBeau contends. They prove only that no document or file

exists containing the names of *all* foods or unpatented drugs, not that no such items have ever received new-drug approval.

LeBeau's legal impossibility argument runs as follows: (1) the FDA requires new-drug approval for food products intended to be sold as drugs; (2) to get new-drug approval a patent must be obtained; (3) but a food item cannot be patented, so a food item can never obtain new-drug approval. Though legal impossibility is a recognized basis for invalidating a statute, *see Tykarsky*, 446 F.3d at 465 (describing the defense as occurring when the law does not proscribe the goal that the defendant sought to achieve), LeBeau's argument is based on a misreading of the pertinent statutory language. The statute requires that "the applicant shall file with the application the patent number and the expiration date of any patent." § 355(b). LeBeau believes that due to use of the word "shall" an applicant *must* provide a patent number on the application or amend the application to include one, meaning that every new drug would have to be patentable. However, reasonably read, "shall" is affected by "any." Section 355(b) merely requires that *if* any patent has been obtained then that number *shall* be included in the new-drug application. If there is no patent, then there is no number that must be included. (*Accord* Doc. 51 at 4 ("A common sense reading of the statute demonstrates that, if there is a patent, the identifying information of such patent must be disclosed. If there is no patent, then obviously no patent information need be disclosed.").) The language does not mandate that the applicant must file for a patent as well as for new-drug approval.

The requirement that an application be amended to include a patent number does not alter this analysis. The statute provides that *if* a patent claiming the drug (or method of using the drug) issues while a new-drug application is pending, the applicant shall

amend the application to include the patent number. § 355(b). Again, if there is no patent, then no patent number will issue and there would be no need to amend to include a patent number.

B. Overbreadth

LeBeau's argument that the statute is overbroad is based on his view that food items are beyond the reach of the FDCA. LeBeau contends that drugs must be man-made, synthetic, patentable items rather than natural food products. He argues that drugs should be determined by their composition rather than by their intended use. *See* § 321(g)(1) (defining (emphasis added) drugs as "articles *intended for use* in the diagnosis, cure, mitigation, treatment, or prevention of disease"). Further, he says, as a policy matter and as supported by legislative history, food products are better treated as supplements rather than drugs.

Much of LeBeau's argument is based on the Food and Cosmetic Act of 1906 (1906 Act). He asserts that the 1906 Act was limited to patented medicines and nostrums (meaning medicines with hidden harmful or addictive ingredients such as opium). However, even assuming that LeBeau's interpretation of the 1906 Act is correct, he was not charged with a crime under the 1906 Act.[5] Even LeBeau admits that Congress changed the law over time to its present form. (Doc. 116 at 3 ("In 1938, the Pure Food Act was amended to include a definition of a 'new drug' and the definition of 'drug' was itself modified in a significant way."); Doc. 116 at 19 ("Years of significant changes to FDCA were in 1938, 1962, 1990 and 1994 . . . .").) And the present form of the statute does not

[5]This court need not delve into the language of the 1906 Act and whether LeBeau's interpretation is correct because he was not convicted under the 1906 Act.

define a drug by its composition but by its use. This court concurs with Magistrate Judge Callahan that LeBeau's argument that food was not intended by the 1906 Congress to be included as drugs "misses the mark because . . . he is not charged with a violation of the Food and Drug Act of 1906. Rather, he is charged with a violation of the FDCA." (Doc. 41 at 6-7.) The text and meaning of the statute under which LeBeau was convicted must be considered rather than what Congress passed or intended in a prior statute that was revised multiple times over 110 years.

As noted by the U.S. Supreme Court, under the 1938 Food, Drug, and Cosmetic Act, which first established procedures for review of drug safety, a new drug was one not generally recognized by qualified experts as safe for its recommended use, and the 1962 amendments redefined the term to denote drugs not generally recognized as safe or effective for their intended use. *Rutherford*, 442 U.S. at 552 & n.8. Thus, the drug definitions that LeBeau says were aimed at patented medicines and nostrums were replaced at least seventy-eight years ago, with little to no suggestion by Congress during the ensuing years that it did not mean what it said in the revised language.

The definition based on intent has been found acceptable by several courts, including the U.S. Supreme Court, without any apparent problems. In *Rutherford*, 442 U.S. 544, the Supreme Court discussed the prohibition on interstate distribution of new drugs and the new-drug definition, without any comment about a possible constitutional issue. *United States v. Millpax, Inc.*, 313 F.2d 152 (7th Cir. 1963), involved the FDCA provisions regarding misbranding of a drug. The Seventh Circuit found no problems with the drug definition based on intent:

> Defendants contend that the preparation known as Millrue is not a drug, but is a food for special dietary use excepted by the Federal Food, Drug, and Cosmetic Act, as amended, from inclusion in the term 'drug.'. . . [H]owever, the intention of the defendants was to have prospective purchasers regard it as a drug and so use it; hence, their own actions classified Millrue as a drug.

Id. at 154. In *United States v. Article . . . Consisting of 216 Cartoned Bottles*, 409 F.2d 734, 739 & n.3 (2d Cir. 1969), the Second Circuit read the statute as Congress's "judgment that a product is subject to regulation as a drug if certain promotional claims are made for it." See also *3 Cartons,* 132 F. Supp. at 573 ("The articles under seizure are all drugs within the meaning of 21 U.S.C.A. § 321(g)(2) since they were intended for use in the treatment, mitigation, and prevention of many disease conditions."). "[I]t is the intended use of an article which determines whether it is a drug, regardless of its inherent properties or dictionary definition." *3 Cartons*, 132 F. Supp. at 573.

LeBeau maintains that the law would be constitutional and acceptable if it defined drugs as articles intended for use in the diagnosis, cure, mitigation, or treatment of disease, leaving out "prevention." But LeBeau was not charged with a crime involving an intent regarding *prevention*. His product labeling indicated that Perfect Colon Formula reduced food allergies, which was a claim about mitigation or treatment, not prevention. So his proffered change would not help him.

Moreover, this court's role is not to change the law to what LeBeau thinks it should be. This court's role is to interpret the law as Congress has passed it, and the FDCA defines a drug by its intended use even regarding prevention. That is so, even if that means that something like honey, cinnamon sugar or garlic fits the definition if "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." *See*

Rutherford, 442 U.S. at 555 ("Under our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy.").

That an article may be recognized as a food does not preclude it from being regulated as a drug. *Nat'l Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 334 (2d Cir. 1977); *216 Cartoned Bottles*, 409 F.2d at 739 n.3 ("If it is to be used only as a food it will come within the definition of food and no other. If it contains nutritive ingredients but is sold for drug use only, as clearly shown by the labeling and advertising, it will come within the definition of drug, but not that of food. If it is sold to be used both as a food and for the prevention or treatment of disease, it would satisfy both definitions . . . ."); *LeBeau*, 786 F. Supp. at 772 n.4 ("Because the Act looks to the purposes for which the products are sold, even seemingly ordinary items, such as honey and cigarettes, may be considered drugs if they are promoted under health claims."); *Gen'l Nutrition, Inc.*, 638 F. Supp. at 558 n.1 ("[S]omething that is a food might also be a drug according to the definitions. (For example, orange juice can be said to be used to prevent disease.[)]".); *United States v. 250 Jars, Etc., of U.S. Fancy Pure Honey*, 218 F. Supp. 208 (E.D. Mich. 1963), *aff'd*, 344 F.2d 288 (6th Cir. 1965); *3 Cartons*, 132 F. Supp. at 573 ("An article which is a food under 21 U.S.C.A. § 321(f) may also be a drug under 21 U.S.C.A. § 321(g)(2) depending upon its intended use.").

That a product occurs naturally does not preclude its regulation as a drug, nor does the fact that the product in one instance may be regarded as a food, prevent it from being regulated as a drug in another. *Nutrilab, Inc. v. Schweiker*, 547 F. Supp. 880, 882 (N.D. Ill. 1982), *aff'd*, 713 F.2d 335 (7th Cir. 1983); *250 Jars*, 218 F. Supp. at 211. For many

years, courts have found that when healing powers are attributed to foods they become drugs within the meaning of the FDCA.

In a case charging that drugs were mislabeled, the Third Circuit found that peppermint tea, wheat germ, and concentrated broth constituted drugs when recommended for gall stones, colic, flatulence, headache, rheumatism, high blood pressure, arthritis, and other ailments. *Hohensee*, 243 F.2d at 370 ("The intended uses of the products . . . were to cure, ameliorate or prevent diseases. The evidence to prove their uses included both graphic materials distributed and testimony of oral representations to users and prospective users."). Another misbranding case involved promotion of honey as a "panacea for various diseases and ailments that have plagued man from time immemorial." *250 Jars*, 218 F. Supp. at 211. The Sixth Circuit upheld the finding that the honey was intended for use as a drug under the definition in § 321(g) at issue in this case. 344 F.2d at 289; *see also Bradley v. United States*, 264 F. 79, 82 (5th Cir. 1920) ("[T]he claimant has put the substance, water, in interstate commerce with the recommendation that it possesses certain elements or ingredients which are curative, or at least alleviative, for the diseases named in the label. He will not be heard now to say the substance recommended is water, and not a drug. Such a construction would nullify the act of Congress."). In *General Nutrition*, the defendants charged with misbranding under the FDCA argued that their product was improperly classified as a drug rather than a food and that the defendants' due process rights were violated. 638 F. Supp. at 558. The district court rejected the challenges, finding the procedural new-drug-approval requirements acceptable. *Id.* at 561. LeBeau may object to this situation, but his complaint is better addressed to Congress than to the court.

LeBeau contends that his product and use of the phrase "reduces food allergies" should have been considered by the government under the Dietary Supplement Health and Education Act of 1994 (DSHEA) rather than the FDCA. (*See* Doc. 113 at 5; Doc. 116 at 5.) He expanded this argument in his reply brief, asserting that the FDA does an "end run around Congressional intent" by claiming that dietary supplements which prevent diseases are drugs. (Doc. 116 at 2.) LeBeau contends that following the passage of DSHEA, the FDA should classify products based on composition rather than intended use. According to LeBeau, "Congressional intent in passing DSHEA was to protect foods and dietary supplements from FDA's arbitrary classification of these nutritional health products as drugs." (Doc. 116 at 16.) He maintains that the government did not have to drag him through "legal mud as an accused drug peddler" but could have looked at the case as one about a dietary supplement. (Doc. 116 at 4.)

LeBeau fails to persuade the court that an amendment from DSHEA took his Perfect Colon Formula outside the drug definition in § 321(g)(1)(B). Notwithstanding any amendments regarding supplements, the pertinent definition of "drug" in (g)(1)(B), the definition of "new drug," and the prohibition against introducing unapproved new drugs into interstate commerce remain on the books. Subsection 321(g)(1)(B), defining "drug" as an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, differs from subsection (g)(1)(C), "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Food items are not exempted from (g)(1)(B), which is what applied to Perfect Colon Formula because LeBeau intended it to treat or mitigate disease. Moreover, review of the definition of "dietary supplement" added by DSHEA indicates that a dietary supplement shall be deemed to be

a food under the FDCA *except* for purposes of § 321(g). Dietary Supplement Health and Education Act, Pub. Law 103-417, 108 Stat. 4325, § 3(a) (codified at 21 U.S.C. § 321(ff)).

Nothing presented by LeBeau persuades the court that the government is prohibited from prosecuting violations of the statutes at issue even though amendments pertaining to supplements may overlap with statutes regarding drugs. The FDCA is a consumer-protection enactment and must be read with that in mind. And the determination that an article is properly regulated as a drug rather than a food is not left to the FDA's unbridled authority but must be in accord with the statutory definitions. *Nat'l Nutritional Foods*, 557 F.2d at 334-35. Moreover, LeBeau's claims regarding supplements that prevent disease do not help him, as this case involves claims of mitigation or treatment, not prevention. *Cf. Whitaker v. Thompson*, 353 F.3d 947, 951 (D.C. Cir. 2004) ("The FDA gave several reasons for classifying claims regarding cure, mitigation, or treatment of an existing disease ('treatment claims') as drug claims and for exempting only health claims that concern reducing the risk of contracting a disease ('prevention claims').").

In sum, LeBeau's overbreadth arguments are rejected.

C. First and Fifth Amendment Arguments

LeBeau's First Amendment freedom-of-speech argument has a few variations. He submits that the statute is unconstitutional because it penalizes one for speech about the use of a product. The court disagrees and finds the statute does *not* penalize a person or another entity for speaking. The statute prohibits the introduction or delivery of a new drug into interstate commerce if it has not been approved by the FDA. The proscribed conduct is distributing the new drug, not speech about the new drug. That the designation "new

drug" depends on the distributor's intent does not alter this analysis. The proscribed conduct remains the distribution, not the speech.

That evidence of intent in this case includes LeBeau's words and writings does not create any constitutional concern. The First Amendment does not prohibit the use of speech as evidence to establish the elements of a crime or to prove intent. *Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993). A product's labeling can be used to infer the seller's intended use and whether the product is an unapproved drug under the FDCA. *Whitaker*, 353 F.3d at 953. The intended use of a product may be determined from its label, accompanying promotional material, advertising, or any other relevant source. *216 Cartoned Bottles*, 409 F.2d at 739 (citing *Hohensee*, 243 F.2d at 370).

LeBeau contends that his speech and use of the claim "reduces food allergies" should be allowed under *Central Hudson* because his words are neither misleading nor illegal. But LeBeau misunderstands the impact of *Central Hudson* for two reasons. First, as set forth above, LeBeau has been convicted of illegal distribution of a product intended to treat a disease or illness, not of illegal speech. LeBeau can say all he wants regarding the treatment properties of the ingredients in Perfect Colon Formula—he can write articles, blog, post or tweet about it as much as he wishes. What he cannot do is distribute a product that he intends for treatment of a disease—and he pled guilty to doing just that.

Second, LeBeau has not discussed the full *Central Hudson* test for whether commercial speech is permissible. While recognizing that the First Amendment protects commercial speech from unwarranted governmental regulation, the Supreme Court in *Central Hudson* found a distinction "between speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties

of speech." 447 U.S. at 561-62 (internal quotation marks omitted). The Court then determined that in commercial-speech cases a four-part analysis applies: (1) whether the commercial speech concerns lawful activity and is not misleading, bringing it under the First Amendment's protection; (2) if yes, whether the governmental interest is substantial; (3) if yes, whether the regulation directly advances the governmental interest asserted, and (4) if yes, whether the regulation is no more extensive than necessary to serve that interest. *Id.* at 566.

LeBeau addresses only the first step of the analysis; he has failed to discuss how steps (2) through (4) should be analyzed in this case. Step (2), in particular, goes against LeBeau. Numerous cases have determined that the federal government maintains a substantial interest in drug regulation. *See Dotterweich*, 320 U.S. at 280; *Hohensee*, 243 F.2d at 370; *Gen'l Nutrition*, 638 F. Supp. at 561; *Marcen Labs.*, 416 F. Supp. at 455 ("Here, the fact that the general public is unable adequately to protect itself in the purchase of food and drugs imposes a high degree of responsibility on those who profit from their manufacture and sale and affects their obligations under regulatory legislation"); *250 Jars*, 218 F. Supp. at 212; *3 Cartons*, 132 F. Supp. at 574. Having failed to adequately discuss whether the pertinent statutes directly advance the government's interest and are no more extensive than necessary, LeBeau has not persuaded the court that he should succeed under the *Central Hudson* test.

Moreover, LeBeau has not convinced this court that his commercial speech concerns lawful activity for passing even step (1). LeBeau's speech occurred while promoting and distributing a product intended for treatment of disease or ailments that had not been approved by the FDA. *See Whitaker*, 353 F.3d at 952-53. In *United States v.*

Caputo, 517 F.3d 935, 940 (7th Cir. 2008), the Seventh Circuit found that unless the underlying drug or medical device could be sold lawfully, there was no need for the court to determine whether statements made regarding use or sale of that item had First Amendment protection: "[Certain prior cases] rest on the assumption that the law allows the activity that the speaker seeks to promote. Here that assumption holds only if AbTox lawfully could sell the large Plazlyte for the (approved) use with solid stainless-steel instruments. Unless the machine itself could be sold lawfully, there were no lawful off-label uses to promote. And the jury found, by its verdicts . . . that the large Plazlyte could *not* lawfully be sold." *Id.*

LeBeau points to *Caronia* to support his argument that he was prosecuted for speech rather than conduct. But his case differs from *Caronia*. Caronia, a pharmaceutical sales representative, was not prosecuted for distribution of an unapproved new drug. Instead, he had promoted an approved drug for off-label use. 703 F.3d at 152. The Second Circuit reversed Caronia's conviction of conspiracy to introduce a misbranded drug into interstate commerce, finding that the record showed that Caronia was prosecuted solely for what he said. At trial, the government argued repeatedly that Caronia was impermissibly promoting a drug for an unapproved use. The theory of prosecution identified Caronia's speech alone as the proscribed conduct, and the jury instructions implied that Caronia's speech was the proscribed conduct. *Id.* at 159-62. The promotional speech was not used merely as evidence of a drug's intended use but rather was the violative conduct itself. *Id.* at 155, 160-61. Further, off-label prescription or use of a drug was legal, as was a doctor's promotion of such use. The FDA's restriction on pharmaceutical representatives thus was content- and speaker-based. *See id.* at 164-65. Doctors and academics could

promote off-label use of a drug without prohibition, while Caronia could not. *Id.* at 165. The court found that the third and fourth prongs of *Central Hudson* thus fell in Caronia's favor. A prohibition on truthful and lawful statements by only one class of speakers did not directly further any goals of preserving the integrity of the FDA's drug-approval process or reduce patient exposure to unsafe or ineffective drugs, nor was the restriction narrowly drawn to further the interests served. *Id.* at 166-68. In contrast to *Caronia*, here distribution of Perfect Colon Formula was not legal.

In *General Nutrition*, the defendants charged with misbranding under the FDCA argued that their prosecution violated their First Amendment right to express opinions regarding their product's alleged nutritional value. 638 F. Supp. at 558. The court rejected the argument:

> [I]t is not speech *per se* which invokes prosecution (or which thereby is "chilled") but rather certain speech in a certain limited context. Just as a constitutionally acceptable prohibition against shouting, falsely, "Fire!" in a crowded room is in no sense a prohibition against all inane or irresponsible utterances, so in this case the government does not challenge the defendants' right to expound on the possible virtues of Gammaprim. It merely contends that in certain circumstances such commentary may become part of the labeling of the product and serve, in a sense, as evidence of a violation of the Act. It is the product and the manner in which the product is marketed which is said to be illegal. . . . The substantial government interest in the goals of the Act justify this extremely narrow encroachment on what is, insofar as it is construed as labeling, clearly commercial speech.

638 F. Supp. at 562.

LeBeau's case is more like *Caputo* and *General Nutrition* than *Caronia*. He was not prosecuted for speech alone, but for circumstances attendant to the distribution of his Perfect Colon Formula.

Next, LeBeau argues that his claim regarding Perfect Colon Formula was based on information from the National Institute of Health's National Library of Medicine (NLM). Therefore, he says, the federal government has essentially endorsed his claim, he was merely sharing that information with others, and the public has the right and ability to look up the same information. According to LeBeau, his reprint of NLM information indicating that an ingredient in Perfect Colon Formula reduces food allergies is equivalent to a consumer looking up that information.

LeBeau confuses the availability of information through the NLM with government endorsement of that information. That the government provides access to medical resources does not mean that information or results of studies available through the library have been endorsed by the government. *See* 42 U.S.C. § 286(a) ("In order to assist the advancement of medical and related sciences and to aid the dissemination and exchange of scientific and other information important to the progress of medicine and to the public health, there is established the National Library of Medicine . . . ."). Again, LeBeau confuses the activity that is proscribed by § 355(a)—distribution—with speech or information.

LeBeau mentions the Fifth Amendment but does not develop this argument except for overbreadth. Regarding due process, LeBeau suggests that the statute improperly allows a product to be designated a drug by a consumer's intent for the product. However, the seller or distributor's intent is what matters for the statute, and LeBeau was convicted based on his intent, as evidenced by his promotions and statements, not the intent of his buyers or anyone reading materials on the NLM website.

As for possible vagueness, the FDCA has been upheld against such challenges. *See United States v. Travia*, 180 F. Supp. 2d 115, 123 (D.D.C. 2001); *Gen'l Nutrition*, 638 F. Supp. at 564 ("[T]he Act provides a clear, albeit complex, scheme designed to safeguard against the sale as medicine of products which may cause indirect harm by not living up to the promises made in connection therewith, or which may cause direct harm, or which are simply harmful *in potentia* because their effects have not been ascertained."); *Marcen Labs.*, 416 F. Supp. at 455.

In his reply brief, LeBeau confusingly asserts that the FDCA's definition of drugs as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" means that his brochure providing information about Perfect Colon Formula—an "article" he wrote—was the "drug" at issue in the government's charge, "not the product Perfect Colon Formula (by its composition)." (Doc. 116 at 4.) However, the argument stretches the words of the statute beyond all reasonable meaning and does not persuade the court that the statute is vague or otherwise unconstitutional.

CONCLUSION

For the above-stated reasons, LeBeau's judgment of conviction is affirmed.

Dated at Milwaukee, Wisconsin, this 3rd day of February, 2016.

BY THE COURT

/s/ C. N. Clevert, Jr.
C.N. CLEVERT, JR.
U.S. DISTRICT JUDGE